BIONIME

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K133003

1. Submitter's Identification:

BIONIME CORPORATION
NO 694, RENHUA ROAD, DALI DIST., TAICHUNG CITY, TAIWAN 412
Contact Person: Mr. Roy Huang
Phone Number: 886-4-23692388
FAX Number: 886-4-22617568

OCT 2 4 2013

Date Summary Prepared: September 23, 2013

2. Name of the Device:
Rightest Control Solution GC300
Rightest Control Solution GC310
Rightest Control Solution GC100
Rightest Control Solution GC110

3. Common or Usual Name: Control Solution

Product Code	Classification	Regulation Section	Panel
JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)	Class I, reserved	21 CFR 862.1660	Clinical Chemistry 75

4. Device Description:

Rightest Control Solution is a single-level, aqueous liquid glucose control solution containing a measured amount of glucose that reacts with the test strips to provide a Quality Control Result. This result should fall within the expected range printed on the Test Strip vial, and will verify if the meter and the test strips are working properly. The Rightest Control Solution has a red color to help users see the solution while dispensing onto a test strip.

Rightest Control Solution is a non-hazardous aqueous glucose control solution containing no human or animal derived materials.

5. Intended Use:

The Rightest Control Solutions GC300 are for use with the Rightest Blood Glucose Meter GM300 and the Rightest Blood Glucose Test Strip GS300 to check that the meter and test strips are working together properly and that the test is performing correctly.

The Rightest Control Solutions GC100 are for use with the Rightest Blood Glucose Meter GM100 and the Rightest Blood Glucose Test Strip GS100 to check that the meter and test strips are working together properly and that the test is performing correctly.

The Rightest Control Solutions GC110 are for use with the Rightest Blood Glucose Meter GM110 and the Rightest Blood Glucose Test Strip GS300 to check that the meter and test strips are working together properly and that the test is performing correctly.

The Rightest Control Solutions GC310 are for use with the Rightest Blood Glucose Meter GM310 and the Rightest Blood Glucose Test Strip GS310 to check that the meter and test strips are working together properly and that the test is performing correctly.

6. Predicate Device Information:

The Rightest Control Solution GC300, GC310, GC100, GC110 are substantially equivalent to the predicate device noted below.

Name:	Rightest Control Solution GC700
Device Company:	Bionime Corporation
510(K) Number:	K110737

7. Comparison to Predicate Devices:

Comparison of similarities and differences:

Item	New Device Rightest Control Solution, GC300, GC310, GC100, GC110	Predicate Device Rightest Control Solution GC700 (k110737)
Similarities		
Intended use	Quality control material to check that the meter and test strips are working properly and that the test is performing correctly	Same

Stability (shelf life)	1.5 years	Same
Stability (open-vial)	3 months	Same
Analyte	glucose	Same
Color	Red	Same
Net fill	4 mL	Same
Differences		
Levels	One	Five
Target range	Level 2 (64-120 mg/dL) (range of midpoint assigned values with various BGMS)	Level 1(44-66 mg/dL) Level 2(83-123 mg/dL) Level 3(163-243 mg/dL) Level 4(231-345 mg/dL) Level 5(351-525 mg/dL) (range of midpoint assigned values with various BGMS)

8. Technological characteristics of the device:

Rightest Control Solution consists of water, d-glucose, inorganic salt, dye and preservative and has been optimized to simulate the response of whole blood on the Rightest Blood Glucose Monitoring Systems. The design and chemical composition is similar to the predicate device. The control solution contains no hazardous, human or animal derived material.

9. Summary of non-clinical tests submitted with the premarket notification for the device:

Tests were conducted to verify specific performance requirements:

a) Value assignment procedure:
Total three lots of control solutions and ten blood glucose meters were evaluated for each test strip type, providing 30 measurements of Rightest Control Solution on each test strip type.

Data from repeated measurement will first be evaluated by ANOVA analysis. Only after passing the ANOVA analysis, the data from repeated measurement can proceed to determine mean/CV to establish an acceptable range. The acceptable range of measurement as ±15% of Mean value to correspond to the value assignment ranges currently provided by using Rightest test strips. The test result should fall within the expected range printed on the Test Strip vial, and will verify if the meter and the test strips are working properly.

b) Closed bottle Stability:
Stability characteristics were determined under unopened conditions in real time and accelerated stability studies to demonstrate an closed shelf-life of 1.5

years (18 months) at the recommended storage temperatures, ranging from 2-30°C (36-86°F).

Opened bottle Stability:
Rightest Control Solution meets stability requirements in real-time stability study as demonstrated by less than 10% bias of week 0 values with an open-vial claim of 3 months (20 weeks).

10. Conclusions:

Results of performance evaluation of the Rightest Control Solution GC300, the Rightest Control Solution GC100, the Rightest Control Solution GC110, and the Rightest Control Solution GC310 demonstrate that the devise is substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2013

BIONIME CORPORATION
c/o Jigar Shah
MDI Consultants, Inc.
55 Northern Blvd. Suite 200
GREAT NECK NY 11021

Re: K133003
Trade/Device Name: Rightest Control Solution GC300
Rightest Control Solution GC310
Rightest Control Solution GC100
Rightest Control Solution GC110
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJX
Dated: September 23, 2013
Received: September 25, 2013

Dear Jigar Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K133003

Device Name: **Rightest Control Solution GC300**

Indications For Use:

The Rightest Control Solutions GC300 are for use with the Rightest Blood Glucose Meter GM300 and the Rightest Blood Glucose Test Strip GS300 to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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Indications for Use

510(k) Number (if known): K133003

Device Name: **Rightest Control Solution GC100**

Indications For Use:

The Rightest Control Solutions GC100 are for use with the Rightest Blood Glucose Meter GM100 and the Rightest Blood Glucose Test Strip GS100 to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): K133003

Device Name: **Rightest Control Solution GC110**

Indications For Use:

The Rightest Control Solutions GC110 are for use with the Rightest Blood Glucose Meter GM110 and the Rightest Blood Glucose Test Strip GS300 to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

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510(k) Number (if known): K133003

Device Name: **Rightest Control Solution GC310**

Indications For Use:

The Rightest Control Solutions GC310 are for use with the Rightest Blood Glucose Meter GM310 and the Rightest Blood Glucose Test Strip GS310 to check that the meter and test strips are working together properly and that the test is performing correctly.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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